## **ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180** 

[EPA-HQ-OPP-2021-0788; FRL-10880-01-OCSPP]

Cyflufenamid; Pesticide Tolerance

**AGENCY**: Environmental Protection Agency (EPA).

**ACTION**: Final rule.

**SUMMARY**: This regulation establishes a tolerance for residues of cyflufenamid in or on sugar beet. Nippon Soda Co., Ltd. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES**: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0788 is available at <a href="https://www.regulations.gov">https://www.regulations.gov</a> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <a href="https://www.epa.gov/dockets">https://www.epa.gov/dockets</a>.

**FOR FURTHER INFORMATION CONTACT**: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

### **SUPPLEMENTARY INFORMATION:**

### I. General Information

## A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B.* How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at https://www.ecfr.gov/current/title-40.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0788 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL* 

*REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0788, by one of the following methods:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC),
   (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <a href="https://www.epa.gov/dockets/where-send-comments-epa-dockets">https://www.epa.gov/dockets/where-send-comments-epa-dockets</a>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <a href="https://www.epa.gov/dockets">https://www.epa.gov/dockets</a>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of March 22, 2022 (87 FR 16135) (FRL-9410-11-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F8950) by Nippon Soda Co., Ltd., ShinOhtemachi Bldg., 2-1, 2-Chome Ohtemachi, Chiyoda-ku, Tokyo, 100-8165, Japan. The petition requested that 40 CFR 180.667 be amended by establishing a tolerance for residues of the fungicide, cyflufenamid, [N(Z)]-N-[[(cyclopropylmethoxy)amino][2,3-difluoro-6-

(trifluoromethyl)phenyl]methylene]benzeneacetamide, in or on sugar beets at 0.07 parts per

million (ppm). That document referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available in the docket, *https://www.regulations.gov*. One comment was submitted by USDA on the notice of filing which supported this action.

Based upon review of the data supporting the petition, EPA has revised the commodity definition from Sugar beet to Beet, sugar, roots; and amended the proposed tolerance from 0.07 ppm to 0.15 ppm. The reason for these changes is explained in Unit IV.D.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyflufenamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyflufenamid follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains

unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections are unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The target organs for cyflufenamid consist of the liver in mice and thyroid in rats. Liver toxicity for mice increased as the duration of exposure increased from subchronic to chronic; increases in toxicity with exposure duration was not observed in rats and dogs. Adverse liver toxicity was only observed in the mouse, with rats and dogs only exhibiting adaptive liver effects.

Thyroid effects observed in the rat included increased follicular cell hypertrophy, increased thyroid weight, and neoplastic thyroid follicular adenomas. There are no concerns for susceptibility associated with cyflufenamid exposure in developing and post-natal animals because the effects observed in the fetal and/or offspring animals in the rat and rabbit developmental and rat two-generation reproduction toxicity studies were at either the same dose or a higher dose than the dose in which effects occurred in the maternal and/or parental animals. Additionally, there are no concerns for neurotoxicity and immunotoxicity.

EPA has classified cyflufenamid as "suggestive evidence of carcinogenic potential", based on the presence of liver tumors in male mice. The point of departure (POD) for the chronic dietary exposure scenario (22 mg/kg/day) is protective of these effects, which were observed at much higher doses (325 mg/kg/day); therefore, quantification of risk using a non-linear approach (i.e., reference dose, RfD, approach) is appropriate to adequately account for all chronic toxicity,

including potential carcinogenicity. Additionally, there are no concerns for genotoxicity and mutagenicity.

## B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime.

Table 1. -- Summary of Toxicological Doses and Endpoints for cyflufenamid for Use in Human Health Risk Assessment

| Summary of Toxicological Doses and Endpoints for use in Dietary and Residential Human |   |                    |             |                         |  |  |  |  |
|---|---|--------------------|-------------|-------------------------|--|--|--|--|
| Health Risk Assessments.  |   |                    |             |                         |  |  |  |  |
| Exposure  | Point of  | Uncertainty /      | RfD, PAD,   | Study and Toxicological |  |  |  |  |
| Scenario  | Departure   | FQPA Safety        | Level of    | Effects                 |  |  |  |  |
|   | (POD)   | Factors            | Concern for |                         |  |  |  |  |
|   |   |                    | Risk        |                         |  |  |  |  |
|   |   |                    | Assessment  |                         |  |  |  |  |
| Acute Dietary   | An acute dietary assessment is not necessary at this time as there were no  |                    |             |                         |  |  |  |  |
| General   | toxicological effects attributable to a single dose within the cyflufenamid |                    |             |                         |  |  |  |  |
| population  | toxicity database   | toxicity database. |             |                         |  |  |  |  |
| (including  |   |                    |             |                         |  |  |  |  |
| infants and   |   |                    |             |                         |  |  |  |  |
| children)   |   |                    |             |                         |  |  |  |  |
|   |   |                    |             |                         |  |  |  |  |
| Females (13-49  |   |                    |             |                         |  |  |  |  |
| years old)  |   |                    |             |                         |  |  |  |  |

|                 | 1  | 1                |                    |  |  |  |  |
|-----------------|--|------------------|--------------------|--|--|--|--|
| Chronic Dietary |  | $UF_A = 10X$     | cRfD =             | Chronic Toxicity /   |  |  |  |
|                 | 22 mg/kg/day   | $UF_H = 10X$     | 0.22 mg/kg/da      | Carcinogenicity Study in Rat                                     |  |  |  |
|                 |  | FQPA SF =        | У                  | (MRID 47620511)  |  |  |  |
|                 |  | 1X               |                    | LOAEL = 115  mg/kg/day,  |  |  |  |
|                 |  |                  | cPAD =             | based on thyroid effects in                                      |  |  |  |
|                 |  |                  | 0.22 mg/kg/da      | both sexes (increased thyroid                                    |  |  |  |
|                 |  |                  | у                  | weight, follicular cell  |  |  |  |
|                 |  |                  |                    | hypertrophy, follicular and                                      |  |  |  |
|                 |  |                  |                    | parafollicular cell  |  |  |  |
|                 |  |                  |                    | hyperplasia, parathyroid   |  |  |  |
|                 |  |                  |                    | hyperplasia) and pancreas  |  |  |  |
|                 |  |                  |                    | (acinar atrophy with chronic                                     |  |  |  |
|                 |  |                  |                    | inflammation) effect in  |  |  |  |
|                 |  |                  |                    | females.   |  |  |  |
| Incidental Oral | NOAEL =  | $UF_A = 10X$     | LOC for            | 90-day Oral Toxicity Study                                       |  |  |  |
| Short-Term      | 23 mg/kg/day   | $UF_H = 10X$     | MOE = 100          | in Dogs (MRID 47620504)  |  |  |  |
| (1-30 days)     |  | FQPA SF =        |                    | LOAEL = 71  mg/kg/day,   |  |  |  |
|                 |  | 1X               |                    | based on decreased   |  |  |  |
|                 |  |                  |                    | bodyweights, brain   |  |  |  |
|                 |  |                  |                    | histopathology, and thymus                                       |  |  |  |
|                 |  |                  |                    | atrophy in both sexes.   |  |  |  |
| Dermal          | A toxicity endpo   | oint was not ide | entified.          |  |  |  |  |
| Short Term      | Systemic toxicit   | y was not seen   | in 28-day derma    | al toxicity in rats up to the limit                              |  |  |  |
| (1-30 days) and | dose (1000 mg/kg/day). There are no concerns for developmental or          |                  |                    |  |  |  |  |
| Intermediate-   | reproductive tox   | cicity or neurot | oxicity in rat and | rabbit studies.  |  |  |  |
| Term            |  | ·                | •                  |  |  |  |  |
| (1-6 months)    |  |                  |                    |  |  |  |  |
| Inhalation      | Oral NOAEL =   | $UF_A = 10X$     | LOC for            | 90-day Oral Toxicity Study                                       |  |  |  |
| Short Term      | 23 mg/kg/day   | $UF_H = 10X$     | MOE = 100          | in Dogs (MRID 47620504)  |  |  |  |
| (1-30 days) and |  | FQPA             |                    | LOAEL = 71  mg/kg/day,   |  |  |  |
| Intermediate-   | Inhalation   | SF=1X            |                    | based on decreased   |  |  |  |
| Term            | Absorption =   |                  |                    | bodyweights, bodyweight  |  |  |  |
| (1-6 months)    | 100% Oral  |                  |                    | gain, food consumption, and                                      |  |  |  |
|                 | Absorption   |                  |                    | liver (\frac{\tau}{\text{liver weight, \frac{\tau}{\text{ALP}}}, |  |  |  |
|                 | 1  |                  |                    | hepatomegaly accompanied   |  |  |  |
|                 |  |                  |                    | by vacuolated hepatocytes  |  |  |  |
|                 |  |                  |                    | and fa deposition), brain  |  |  |  |
|                 |  |                  |                    | histopathology, and thymus                                       |  |  |  |
|                 |  |                  |                    | atrophy in both sexes.   |  |  |  |
| Cancer          | HED classified cyflufenamid as "suggestive evidence of carcinogenic        |                  |                    |  |  |  |  |
|                 | potential" and quantification of risk using a non-linear approach (i.e., R |                  |                    |  |  |  |  |
|                 |  |                  |                    |  |  |  |  |
|                 | potential" and q   | uantification of | f risk using a non |  |  |  |  |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed adverse-effect level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed adverse-effect level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies).

# C. Exposure Assessment

- 1. Dietary exposure from food and feed uses. In evaluating dietary exposure to cyflufenamid, EPA considered exposure under the petitioned-for tolerances as well as all existing cyflufenamid tolerances in 40 CFR 180.667. EPA assessed dietary exposures from cyflufenamid in food as follows:
- i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for cyflufenamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.
- ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (USDA's NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100% crop treated (100% CT) for all commodities. Anticipated residues and/or percent crop treated (PCT) data were not used.
- iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to cyflufenamid. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *Chronic exposure*.
- iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residues and/or PCT information in the dietary assessment for cyflufenamid.

  Tolerance level residues and/or 100% CT were assumed for all food commodities.
- 2. Drinking water, non-occupational, and cumulative exposures. Drinking water and non-occupational exposures are not impacted by the proposed use of cyflufenamid on sugar beet, and thus have not changed since the last assessment. For a summary of the dietary exposures from drinking water, see Unit III.C.2. of the February 9, 2018, rulemaking (87 FR 5711). There are no proposed residential uses for cyflufenamid at this time; however, there are existing uses that result in potential post-application residential exposures which have been previously assessed

using current data and assumptions. The registered uses anticipated to result in post-application dermal exposure to cyflufenamid include commercial treatment of outdoor ornamentals. Because the Agency has not identified a dermal endpoint, a quantitative residential dermal exposure assessment was not necessary and was not conducted. EPA's conclusions concerning cumulative risk remain unchanged from Unit III.C.4. of the February 9, 2018, rulemaking.

D. Safety Factor for Infants and Children.

- 1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.
- 2. Prenatal and postnatal sensitivity. There are no concerns for susceptibility associated with cyflufenamid exposure in developing and post-natal animals. Additionally, there are no concerns for neurotoxicity and immunotoxicity.
- 3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:
  - i. The toxicity database for cyflufenamid is complete.
- ii. There is no indication that cyflufenamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that cyflufenamid results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyflufenamid in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyflufenamid.

## E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

- 1. Acute risk. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyflufenamid is not expected to pose an acute risk.
- 2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyflufenamid from food and water will utilize 1.3 % of the cPAD for all infants < 1 year old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyflufenamid is not expected.
- 3. *Short-term risk*. A short-term adverse effect was identified for inhalation and oral exposures; however, cyflufenamid is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential

exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for cyflufenamid.

- 4. *Intermediate-term risk*. An intermediate-term adverse effect was identified; however, cyflufenamid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for cyflufenamid.
- 5. Aggregate cancer risk for U.S. population. EPA has determined that quantification of risk using the RfD approach is appropriate and will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to cyflufenamid. Based on the conclusions of the chronic dietary assessment, EPA concludes that exposure to cyflufenamid is unlikely to pose an aggregate cancer risk.
- 6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyflufenamid residues.

#### IV. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodology high-performance liquid chromatography method with tandem mass spectrometry detection (HPLC/MS/MS), Method No. RD-01307 is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical

Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for cyflufenamid.

#### C. Revisions to Petitioned-For Tolerances

The Agency is establishing a tolerance for beet, sugar, roots at 0.15 ppm, which is higher than what the petitioner requested at 0.07 ppm based on Organization for Economic Cooperation and Development calculation procedures. Additionally, the Agency is establishing the tolerance for "beet, sugar, roots" rather than "sugar beet" to reflect the common commodity vocabulary currently used by the Agency.

#### V. Conclusion

Therefore, a tolerance is established for residues of cyflufenamid, [N(Z)]-N-[[(cyclopropylmethoxy)amino][2,3-difluoro-6-

(trifluoromethyl)phenyl]methylene]benzeneacetamide, in or on Beet, sugar, roots at 0.15 ppm.

### VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these

types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 4, 2023.

## Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

# PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL

# **RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority**: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.667, amend the table in paragraph (a) by adding a heading to the table and adding in alphabetical order the entry "Beet, sugar, roots" to read as follows:

# § 180.667 Cyflufenamid; tolerances for residues.

Table 1 to Paragraph (a)

| Commodity          |   |   |   | Parts per million |   |   |      |  |
|--------------------|---|---|---|-------------------|---|---|------|--|
|                    | * | * | * | *                 | * | * | *    |  |
| Beet, sugar, roots |   |   |   |                   |   |   | 0.15 |  |
|                    | * | * | * | *                 | * | * | *    |  |

\* \* \* \* \*

[FR Doc. 2023-09872 Filed: 5/9/2023 8:45 am; Publication Date: 5/10/2023]